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Method for Anterior wiate Ligament Reconstruction Field of the Invention

The present invention relates to a method for the reconstruction of the anterior cruciate ligament of a patient. More particularly it relates to such a method in which a tendon graft is used to replace the ruptured anterior cruciate ligament.

Background Art

As is well known the human knee comprises an articulation of the femur, the tibia and the patella. The femur and the tibia are maintained in a condition of stable articulation by a number of ligaments of which the principal ones are the anterior and posterior cruciate ligaments and the lateral ligaments. The rupture of the 15 anterior cruciate ligament is relatively commonly encountered as a result of sporting injury or the like. This rupture leads to knee instability and can be a debilitating injury.

There have been a number of procedures designed to 20 reconstruct the anterior cruciate ligament. Initially, attempts were made to replace the anterior cruciate ligament with tendons harvested from elsewhere in the These tendons were connected respectively to the femur and the tibia by staples, screws or the like 25 inserted exteriorly into the bone and forming an external attachment to which the tendon could be connected externally of the bone. In some cases, the tendon passed over the top of one of the femoral condyles before attachment to the femur and in other cases a hole was 30 drilled through the femur from outside the bone into the intercondylar notch. These attempts at anterior cruciate ligament reconstruction had mixed success. The tendon tended to break at its point of connection to the bone, or become loose over time, indicating that the tendon-bone

interface was crucial for effective anterior cruciate

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ligament reconstruction.

These problems led to the use of bone-tendon-bone grafts generally harvested from mid-third patella tendon with a bone block at each end. Each bone block is 5 inserted into an appropriate hole drilled in the femur or the tibia and secured in place by a screw driven between the wall of the hole and the bone block. While this system has been very successful in many respects a significant number of patients continue to have patella-femoral problems, especially over the mid-third patella tendon donor site.

In an effort to overcome these problems it has been proposed to suture hamstring tendon to a bone block derived from coring the tibial tunnel and to thereby manufacture a bone/tendon/bone graft similar to a 15 mid-third patella tendon graft. The present inventors have found that the bone quality is extremely variable. This results in poor fixation and poor intra-operative pull-out strength in some cases. This procedure was also 20 found to be a very demanding surgical procedure, and therefore difficult to reproduce.

Disclosure of the Invention

The present invention consists in a method for the reconstruction of the anterior cruciate ligament of a patient comprising the steps of:-

- forming a tendon graft from tendon, other soft tissue or artificial tendon;
- forming a hole through the patient's femur from a suitable point in the intercondylar notch therein anteriorly and laterally, the cross-sectional area of at least an end portion of the hole through the femur adjacent the intercondylar notch being sufficient to receive an end of the tendon graft and a suitable screw,
- peg or other fixation device having a leading end and a 35 trailing end;

- c) forming a suitably positioned hole through the patient's tibia opening at one end adjacent the cross-sectional medial tibial spine of the tibia of an area sufficient to receive the other end of the tendon 5 graft;
 - d) drawing one end of the tendon graft into the enlarged end portion of the hole in the femur and simultaneously or sequentially drawing the other end of the tendon graft into the hole in the tibia;
- 10 e) inserting the leading end of a fixation device into the hole in the femur from the intercondylar notch end thereof until the trailing end of the fixation device is at least adjacent that end of the hole, and the tendon graft is pressed directly and firmly against a sidewall
- of the hole in the femur by the fixation device; and

 f) after tensioning the tendon graft appropriately,
 securing the other end of the tendon graft to the tibia.

It has been surprisingly found that, even without the presence of a bone block, a screw or other similar

20 fixation device can adequately secure the tendon graft in place in both the femoral hole and the tibial hole. The initial pull out strength is high and with time permanent fixation is achieved through bone ingrowth into the tendon graft.

- In a preferred embodiment of the invention the tendon graft comprises tendon or tendons derived from the hamstring tendons of the patient or from the achilles tendons of cadavers. Most preferably, the tendons are the semitendonosus and gracilis tendons of the patient
- harvested from the same leg as has the deficient anterior cruciate ligament. The invention could be practised using artificial tendon material or other bodily soft tissue such as ligament. Suitable synthetic plastics materials have been proposed for use in biological applications and
- 35 could be used in place of natural tendon.

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The tendon or tendons forming the tendon graft are preferably doubled over about their mid-point and trimmed to a desired length. The doubled over end and the free ends are preferably then each bound together over a length approximately equal to the length of the tendons that will extend through the holes in the femur and the tibia. Preferably, the ends of the tendon or tendons will be bound together using a Krakow suture or modified baseball stitch. A suture may also be connected to the tendon graft at each end. This suture may be used to draw the tendon graft through the respective holes and to tension the tendon graft prior to insertion of the fixation device in the tibial hole.

It is preferred that the hole in the femur is 15 initially drilled as a guide hole of sufficient diameter to receive a suitable guide pin. The hole is then enlarged at least to a depth sufficient to receive an end portion of the tendon graft. This enlargement may be carried out using a cannulated drill guided on the guide 20 pin. It is preferred, however, that the hole is enlarged using a rotary awl that enlarges the hole by compressing or compacting the bone around the original hole. particularly preferred that the size of the enlarged portion of the hole is sized to the size of the tendon graft to be placed in the hole. The cross-section area of the hole is desirably equal to or only very slightly greater than the cross-sectional area of the end portion of the tendon graft to be placed in the hole. fixation device has an enlarged head at its trailing end, 30 it is desirable that the femoral hole, has adjacent the intercondylar notch a short section of further increased cross-sectional area to receive the head of the fixation Similarly it is preferred that the external end of the tibial hole has a short section of further increased cross-sectional area.

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The tibial hole is preferably formed by drilling a hole having a cross-sectional area just sufficient to receive the other end portion of the tendon graft. tendon graft may vary in cross-sectional area along their length it is usual to position the larger end of the tendon or tendons in the tibial hole. A guide hole is preferably drilled from the outside and is guided so that at its exit from the tibia it will be at the coronal level of the median tibial eminence 2/3 of the way across the 10 notch, lateral to medial, so as to remove the anterior cruciate ligament stump. The aim of positioning is so that the final hole causes the graft to arise from the centre of the notch coronally, sufficiently posterior to avoid impingement with the roof of the notch at full 15 extension of the knee. The point of entry into the tibia is preferably selected such that the length of the hole is just sufficient to receive the other end portion of the tendon or tendons when the one end has been secured in the femoral hole. A guide pin is preferably placed through 20 this guide hole and the hole enlarged to the desired cross-sectional area by a cannulated rotary awl guided

In another aspect the present invention consists in a method for forming a hole in bone comprising the steps of

25 a) drilling a guide hole in the bone;

along the guide pin.

- b) inserting a guide wire into the guide hole, and
- c) passing a cannulated rotary awl down the guide wire while causing the awl to rotate to enlarge the guide hole to a desired size by compressing or compacting the bone around the guide hole.

The one end of the tendon graft is preferably drawn into the femoral hole by a suture that is connected to one end of the tendon or tendons and is positioned to extend through the tibial hole, through the knee joint, through the femoral hole and out of the patient's thigh. As the

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suture is pulled so the tendon graft is drawn through the tibial hole into the femoral hole. Using this method when the one end of the tendon graft is firmly drawn into the enlarged portion of the femoral hole the other end of the 5 tendon graft will be just drawn into the outside of the tibial hole.

The tendon graft is preferably fixed in the femoral hole by being directly and firmly pressed against the sidewall of the hole by a screw. The screw is most preferably formed with a thread devoid of an outermost cutting line so that neither the tendon or tendons nor the suture stitches around them will be cut by a sharp thread on the screw. The screw preferably also has a hemispherical head and is placed in the hole anteriorly of 15 the tendon graft. This causes the tendon graft to firstly be spread as an arc around a posterior part of the circumferences of the screw and secondly causes the tendon graft to be curved smoothly around the head as it exits the femoral hole. Instead of a screw the tendon graft may 20 be held in place in the femoral hole by a suitable pin, peg or other device that will force the tendon graft directly and firmly against the sidewall of the femoral The head of the screw, pin, peg or the like should preferably be just below the surface of the femur. ensures that the tendon graft is pressed against the sidewall of the femoral hole up to the condylar notch end of the hole. This prevents "pistoning", i.e. movement under cyclic load of the tendon or tendon bundle longitudinally of the hole, of the tendon graft in the hole as happened with many prior art systems. "pistoning" of the tendon or tendon bundle prevents bone ingrowth into the tendon graft and therefore hinders the permanent fixation of the tendon to the bone.

After the one end of the tendon graft is secured in 35 the femoral hole a suture connected to the other end of

the tendon graft is drawn tight and a suitable screw, pin, peg or the like is preferably inserted into the tibial hole from its outside end. The length of the screw, pin, peg or the like is preferably of such a length that, when its head is inserted until it is just below the outside surface of the tibia, it will extend substantially the full length of the tibial hole. The screw, pin or peg in the tibial hole the tibial hole serves to force the other end of the tendon graft into direct and firm contact with the side wall of the tibial hole. The tibial end of the tendon graft may, alternatively, be held in place by an exterior fixing such as a staple.

Brief Description of the Drawings

- Fig. 1 is a schematic perspective view of a patient's knee showing the position of the semitendonosus and gracilis tendons and the incision through which it is harvested;
 - Fig. 2 is a perspective view of the harvested tendon prepared as a graft construct;
- Fig. 3 is schematic perspective view of the patient's knee showing the positioning of an arthroscope and the drilling of a guide hole for the formation of a femoral hole to receive one end of the tendon graft;
- Fig. 4 is a schematic perspective view showing a 25 cannulated awl on a beath pin being used to form the enlarged femoral hole;
 - Fig. 5 is of an enlarged perspective view of the cannulated awl used in the procedure depicted in Fig. 4 incuding cross-sectional views along sections A-A and B-B;
- Fig. 6 is a schematic perspective view showing the drilling of a guide hole for a tibial hole to receive the other end of the tendon graft;
 - Fig. 7 is schematic perspective view of drawing the tendon graft through the tibial hole into the femoral hole;
- Fig. 8 is a schematic perspective view showing the

placement of a screw to secure the one end of the tendon graft in the femoral hole;

Fig. 9 is a schematic perspective view showing the placement of a screw to secure the other end of the tendon graft in the tibial hole;

Fig. 10 is a vertical sectional view of a screw positioned in the femoral hole and securing the one end of the tendon graft

Best Mode of Carrying out the Invention

10 Operating Protocol

The following protocol assumes the operator will be securing the graft 10 on the femoral side 11 from within the joint and on the tibial side 12 externally. graft 10 consisting of semitendonosus and gracilis 15 tendons 13 and 14 respectively is also assumed.

Preparation

Routine arthroscopy is performed prior to commencement of reconstruction of the anterior cruciate Portal placement is critical and can be 20 described thus: the anterolateral portal (not shown) is towards the top of the lateral triangle soft spot. made with a transverse stab incision, aimed at the intercondylar notch 15. The anteromedial portal 16 is lower than usual, being 1cm above the joint line and at 25 the fat pad reflection, with the blade aimed slightly up and towards the intercondylar notch.

At this time, using the arthroscope in the anterolateral portal, any meniscal repair or excision is carried out as well as any debridement required for adequate visualisation of the joint in general and the 30 notch in particular. Often this requires partial excision of the fat pad and particularly careful clearing of the notch surface of the lateral condyle of the femur. scar tissue associated with the ruptured cruciate, the stump of the anterior cruciate ligament and the plica

interarticularis should also be debrided. A curette is used to clear the lateral wall of the notch and a suction shaver may be used to remove the resultant debris.

The semitendonosus and gracilis tendons 13 and 14 are 5 then harvested as graft material. This should be done in whatever fashion the operator is comfortable with, however, a single incision 17 approximately 30 millimeters is all that is required. The incision is medial to the tibial tubercle at the level of the pes anserine insertion. The harvesting of the semitendonosus and gracilis tendons 13 and 14 should result in at least 22cm of the tendons. Separation of the tendon should occur at the musculo-tendinous junction. Care should be taken in harvesting the tendons to ensure the accessory distal 15 insertions of the semitendonosus in particular are divided and do not divert the harvesting tool into the body of the tendon.

After the tendons 13 and 14 are cleared of adherent muscle fibers their length should be measured and the mid-point determined, ideally this is 11cm from the distal insertion of the tendons. The broad surface of the semitendonosus 13 is wrapped around the tendon mass using this tendon to give a smooth exterior surface to the The two tendons 13 and 14 are then doubled over 25 a No. 5 suture 18 which will subsequently act as a lead pulling suture. With the tendons doubled over this lead suture by a clip on the free end (not shown), a No. 1 ethybond suture 19 is inserted into the folded end. four strand hamstring tendon complex 10 is sutured with a 30 modified double baseball stitch to hold them together so that they resist damage upon interference fit screw The femoral insertion end 22 should consist of at least 3 stitches securing the whole of the tendon mass for a length of 20mm. At the free and tibial insertion end 23 of the tendons 10 another suture 21 is used along 35

approximately 30mm of length, again, in a modified double baseball stitch pattern. The 11cm long 4 strand tendon graft 10 has now been constructed.

A mark is now made, using a sterile marking pen, on the tendon graft 30mm distal to the double folded end of the tendon graft complex. This mark is used to ensure the tendon graft will be pulled up sufficiently into the femoral drill hole. The diameter of the tendon graft is now measured at both the proximal and distal ends, using a tube gauge. These diameters are noted for appropriate awl sizing. Any free tissue in the graft 10 which may bunch up and obstruct the passing of the graft 10 through the tibial and femoral drill holes should now be noted and excised.

Having taken the graft, the arthroscope 24 is then inserted into a central portal through a stab incision 25 over the patella tendon, just below the inferior pole of the patella (not shown), thereby allowing better visualisation of the back of the notch 15. Often it is found that further clearing of the lateral wall of the notch 15 is required. This should be performed until the capsular attachment is clearly visualised and palpated with a probe.

Femoral Drilling

A point 30° from the top of the notch (11 o'clock in a right knee; 1 o'clock in a left knee) and 5mms from the back of the notch 15 on the lateral wall is then identified and indented with a burr. Care must be taken to avoid identifying the ridge of the anterior edge of the original ACL attachment as the back of the notch (resident's ridge). This error will lead to the femoral tunnel being too anterior, compromising graft function. A 4.5mm drill 26 is then passed into the joint through the medial portal 16 and the tip placed in the burr hole while the knee is held at 90° (the use of standard tissue

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protecting sleeves is recommended). The drill is the spun a few turns to bed it into this depression .

Holding the drill tip in the shallow hole thus created the knee is pushed into as much flexion as it will achieve. Directing the drill approximately 20° anteriorly and 30° laterally with respect to the femur, a guide hole is then made, with drilling ceasing as soon as the outer cortex is felt to have been pierced. Withdraw the drill 26 and inspect the hole 29 to confirm position by passing the arthroscope deep into the notch.

With the knee at 90° flexion, a beath pin 27 is then passed through the medial portal and up to the entrance of the guide drill hole under direct vision. Care should be taken not to pass the pin 27 through the posterior cruciate ligament. The knee is flexed maximally and the pin 27 is passed up the guide hole and out through This pin 27 serves as the guide for a cannulated stepped awl 28. With the knee held fully flexed a stepped awl 28 of minor diameter matching the tendon graft, is then passed along the pin 27 and, under direct vision, the femoral hole 29 made. The stepped awl 28 has a diameter 31 which corresponds to that of the measured tendon graft, and cutting ears 32,25mm distal from the tip (9 or 10mm diameter) and 10mm in length, to accommodate the screw head at the graft origin. should continue up to a mark just distal to the cutting The awl 28 is formed with flutes 30 at its leading end that compact the bone surrounding the hole to enlarge it.

The awl 28 is then removed and a nylon loop (not shown) threaded into the eye 31 of the beath pin 27. With the loop end held, the pin 27 is drawn out of the femur and the free ends of the nylon and drawn through the femoral hole 29 and out of the thigh. Smoothing of the edge of the femoral hole and debridement of any loose

tissue is now carried out.

The tibial hole is then made with the use of a The tip 34 of the guide 33 is passed through the anteromedial portal 16 and placed on a line from the anterior horn of the lateral meniscus to the medial tibial spine and medially, one quarter of the way across the intercondylar notch, that is just medial to the medial tibial spine. The drill guide 33 then passes through the distal skin incision 17 used for the harvesting of the hamstring tendon graft 10 and measures 40-45 mm distal from the cruciate ligament tibial attachment. The 4.5 mm drill 35 is used to establish the line until the cortex of the tibial plateau is reached, whereupon the guide is removed and the drilling completed under direct vision. The final position may be find tuned by hand, so that the

The final position may be find tuned by hand, so that the final drill position will abut the medial eminence and remove the anterior cruciate ligament stump. Having achieved satisfactory placement of the 4.5mm drill 35, a 2.0mm guide wire (not shown) is passed into the hole.

The guide wire should intersect the PCL near its femoral insertion to indicate correct drill hole placement and alignment. A cannulated awl (not shown but similar to awl 28) of minor diameter equal to that of the tendon graft's distal end can now be introduced over the guide

wire. Drilling of the tibial hole 36 should continue up to a marker just distal to the cutting ears. When tibial hole enlargement is completed, the soft tissue at the entry to the joint can be cleared with a shaver.

With the knee at 90° flexion, a pair of grasping 30 arthroscopy forceps (not shown) are then passed through the tibial drill hole until the jaw of the forceps is around the nylon threads previously passed through the joint. The looped end of the thread is then pulled through the tibial drill hole 36. The thread now passes 35 through the tibial and femoral drill holes and is used to

pass the leading graft thread 18. The threads 18 from the tendon graft 18 complex 10 are placed through the lead thread loop and pulled proximally. Using these threads 18, the graft 10 is drawn into the joint and then into the femoral hole 29 until the mark made earlier, 30mm from the doubled end 22 of the graft 10, is at the entrance to the femoral drill hole 29. Care should be taken as the graft 10 is pulled up that the distal insertion of the tendon graft 10 is not preventing the graft from passing up the 10 tibial hole 36. Some degree of release may be required to achieve complete passage of the graft. A guide wire 37 is then introduced through the anteromedial portal 16 and the tip placed at the femoral hole 29 entrance, between the edge of the hole and the tendon graft 10. The knee is then fully flexed and the guide wire 37 runs up 25mm into 15 the tunnel between the graft 10 and the femoral hole 29 wall.

Once the surgeon is satisfied that the graft 10 and the wike 37 are correctly placed, by direct vision, a Donjoy RCI screw (made according to US Patent Application 20 08/039056) 38 and a driver (not shown) are run over the wire 37 and into the joint. Once the tip of the screw 38 is engaged between the graft 10 and the bone surface a firm tap with a mallet to encourage thread grip and to bed 25 the graft down into the hole may be used, while the proximal threads 18 and the distal threads 21 on the graft 10 are kept taut, minimizing the tendency of the screw to wind up the graft 10. Then maintaining traction on the threads 18 and 21 used to hold the graft in the femoral drill hole 29, the screw 38 is advanced until the head is 30 completely within the femoral hole 29. The head of the screw should be completely buried within the hole 29 and not visible once the screwdriver is removed. screw not be advancing as it is rotated, it should again be tapped with a mallet to re-establish bony interlock and

free any obstruction to its progress prior to continuing to screw in. With the knee still fully flexed the guide wire 37 is removed, once the surgeon is comfortable with the fixation and placement of the screw 38.

Having fixed the femoral end of the tendon graft 10, the knee is placed at 90° flexion and the tibial end 23 drawn down firmly, thereby applying tension to the graft 10. Isometricity may be tested at this time as the knee is extended and flexed. Having achieved the desired 10 tension and positioning of the graft 10 a guide wire 39 is inserted between the graft and the bone of the tibia inferiorly. While maintaining distal tension on the graft 10, and holding the knee at $30-45^{\circ}$ of flexion, a screw 41 similar to screw 38 is advanced until a partial 15 grip is obtained. the knee is then gently extended to $0^{\rm O}$ and the screw 41 then advanced fully until the head is in the femoral hole 36 and a firm interference grip is achieved. Full extension must be achieved prior to completion of the insertion of the screw 41. The guide 20 wire 39 is then removed.

The motion of the knee, Lachman test, anterior draw and pivot shift test are finally checked. The knee is copiously irrigated to remove debris. A drain is passed into the joint using the arthroscopic procedure and 25 directly laterally.

Routine closure and post-operative care is followed.